

REMARKS

Status of the claims

Claims 1, 3, 5-7, 9-21 and 46-50 are pending in this application.

Rejection over Clerc and Bolz

Claims 1, 3, 5-7, 9-21 and 46-48 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Clerc, US 2002/0165601 (Clerc) in view of Bolz et al., US 6,287,332 (Bolz). This rejection and its accompanying remarks are respectfully traversed.

For a proper obviousness rejection, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103(a). The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), quoting *In re Kahn*, 441 F.3d 977, 988, (Fed. Cir. 2006). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

According to the Office Action, Clerc discloses an implantable medical device comprising a biodegradable inner core (stent 102) and a biodegradable covering material (106) completely covering the inner core 102 (see Fig. 2A). However, it is clear from Figs. 2A-2B that the covering material 106 only covers the outer (abluminal) surface of the stent 102. The inner (luminal) surface of the stent 102 is exposed to the blood.

As indicated by the Examiner, Clerc describes polycaprolactone as a biodegradable covering material 106. However, because the stent 102 is exposed to the blood, the biodegradable covering material 106 does not completely cover the inner core material as claimed.

With regard to the use of a hydrophobic surface erodable polymer as a covering material (claim 5), more particularly, the use of a polyamide, a polyorthoester or a polyanhydride as a covering material (claims 48-50), as indicated in the present specification, surface erodable polymeric materials are materials in which bulk mass loss occurs primarily at the surface of the

material, rather than throughout the bulk of the coating material. By confining bulk mass loss to primarily the surface, the coating material acts a barrier to penetration by body fluids that would otherwise penetrate into the core material. This allows the medical device to maintain its mechanical properties for a time, after which penetration of body fluids into the core renders it more flexible. This feature is neither taught nor suggested by Clerc, because the inner core 102 is exposed to bodily fluid (blood) from the start.

It is noted that surface erodable polymers are also advantageous in that they can be modified to control the rate of surface erosion by, for example, adding basic or acidic additives, depending, for example, on whether degradation primarily proceeds by acid catalyzed or base-catalyzed hydrolysis. Polyorthoesters, for example, degrade primarily by acid catalyzed hydrolysis. Thus, addition of an acidic substance to a polyorthoester may be used to increase the rate of surface bioerosion, whereas the addition of a basic substance may be used to decrease the rate of surface bioerosion. In addition, the thickness of the surface erodable polymer on the core material can be selected to extend or shorten the time period during which erosion occurs and thus extend or shorten the time period prior to substantial penetration of body fluids into the core.

With regard to the particular hydrophobic surface erodable polymers of claims 48-50 (polyamide, polyorthoester and polyanhydride), the Examiner has asserted that it would be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. This, however, is a mere conclusory statement, without articulated reasoning with some rational underpinning to support the legal conclusion of obviousness, which is prohibited by *KSR* (see above). See also the USPTO publication entitled “Formulating And Communicating Rejections Under 35 U.S.C. 103 For Applications Directed To Computer-Implemented Business Method Inventions”, which states the following: “A simple statement that a difference is a ‘design choice’ or ‘lacks an advantage or unexpected result’ is insufficient rationale to support a well written and legally sufficient rejection. These are conclusions, not statements of fact.” Here, the Examiner has provided no rationale for why one would substitute these *surface erodible* materials for the materials taught in Clerc. In fact, Clerc is completely unconcerned with whether or not the polymeric materials used therein are surface or bulk erodible.

As noted by the Examiner, Clerc fails to disclose that the biodegradable inner core material is selected from a metallic material and a ceramic material. The Examiner turns to Bolz, which describes bioresorbable metal stents, to make up for this deficiency in Clerc.

Bolz, however, does not make up for the above noted deficiencies in Clerc. For example, as with Clerc, Bolz fails to teach or suggest a biodegradable covering material that completely covers an inner core material. In addition, Bolz does not teach or suggest a hydrophobic surface erodable polymer for use as a biodegradable covering material (see claims 5 and 48-50). Indeed, Bolz does not teach or suggest polymeric coatings at all.

For at least the above reasons, reconsideration and withdrawal of this rejection under 35 U.S.C. 103(a) are thus respectfully requested.

CONCLUSION

Applicant submits all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order that any outstanding issues be resolved.

FEES

If there are any fees due and owing in respect to this amendment, the Examiner is authorized to charge such fees to deposit account number 50-1047.

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Respectfully submitted,

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